

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

ALDERSON *et al.*

Patent No.: 7,223,724 B1

Issued: May 29, 2007

For: **Use of Vascular Endothelial
Growth Factor to Treat
Photoreceptor Cells**

Confirmation No.: 1320

Art Unit: 1647

Examiner: Landsman, Robert S.

Atty. Docket: 1488.100000F/PAJ/LMB

Request for Certificate of Correction Under 37 C.F.R. § 1.322

Attn: Certificate of Correction Branch

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

It is hereby requested that a Certificate of Correction under 37 C.F.R. § 1.322 be issued for the above-captioned United States Patent. This Certificate of Correction is being requested due to mistakes which appear in the printed patent. These mistakes were made by the U.S. Patent and Trademark Office.

Specifically, the printed patent contains the following errors for which a Certificate of Correction is respectfully requested:

Requested Change	Location of Support in File History
In column 127, claim 1, please delete "amino acids 108 to 188" and insert therein -- amino acids 108 to 188 --.	Amendment and Reply filed on October 12, 2004
In column 127, claim 1, please delete "amino acids 108, 133, 139, 142, 143, 150, 186 and 188" and insert therein -- amino acids 108, 133, 139, 142, 143, 150, 186 and 188 --.	Amendment and Reply filed on October 12, 2004

In column 128, claim 4, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 5, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 6, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 7, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 8, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 9, please delete "administered at a dose between about 0.05 mg/kg and about 5 mg/kg" and insert therein -- administered at a dose between about 0.05 mg/kg and about 5 mg/kg --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 10, please delete "amino" and insert therein -- amino --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 13, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 14, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 15, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 16, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 17, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 18, please delete "administered" and insert therein -- administered --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 19, please delete "ischemic" and insert therein -- ischemic --.	Amendment and Reply filed on October 12, 2004
In column 128, claim 20, please delete "ischemic" and insert therein -- ischemic --.	Amendment and Reply filed on October 12, 2004

In support of these corrections, a copy of the Amendment and Reply filed on October 12, 2004 is enclosed.

Remarks

The above-noted corrections do not involve such changes in the patent as would constitute new matter or would require reexamination.

A completed Form PTO/SB/44 accompanies this request, with the above-noted corrections printed thereon. Accordingly, a Certificate of Correction is believed proper and issuance thereof is respectfully requested.

The Commissioner is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Lori M. Brandes
Agent for Patentees
Registration No. 57,772

Date: 8/13/2007

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UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 2

PATENT NO: 7,223,724 B1

DATED: May 29, 2007

INVENTOR(S): ALDERSON *et al.*

It is certified that error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below.

In column 127, claim 1, please delete "am1no acids 108 to 188" and insert therein -- amino acids 108 to 188 --.

In column 127, claim 1, please delete "am1no acids 108, 133, 139, 142, 143, 150, 186 and 188" and insert therein -- amino acids 108, 133, 139, 142, 143, 150, 186 and 188 --.

In column 128, claim 4, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 5, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 6, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 7, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 8, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 9, please delete "adm1nistered at a dose between about 0.05 mg1kg and about 5 mgfkg" and insert therein -- administered at a dose between about 0.05 mg/kg and about 5 mg/kg --.

In column 128, claim 10, please delete "am1no" and insert therein -- amino --.

In column 128, claim 13, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 14, please delete "adm1nistered" and insert therein -- administered --.

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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Washington DC 20005-3934
Atty. Dkt. No. 1488.100000F/PAJ/LMB

This collection of information is required by 37 CFR 1.322, 1.323 and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 2 of 2

PATENT NO: 7,223,724 B1

DATED: May 29, 2007

INVENTOR(S): ALDERSON *et al.*

It is certified that error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below.

In column 128, claim 15, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 16, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 17, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 18, please delete "adm1nistered" and insert therein -- administered --.

In column 128, claim 19, please delete "ischem1c" and insert therein -- ischemic --.

In column 128, claim 20, please delete "ischem1c" and insert therein -- ischemic --.

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This collection of information is required by 37 CFR 1.322, 1.323 and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



1647
JFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Alderson et al.

Docket No.: PF112U1

Application No.: 09/499,468

Confirmation No.: 1320

Filed: February 7, 2000

Group Art Unit: 1647

For: Use of Vascular Endothelial Growth Factor 2 to
Treat Photoreceptor Cells (as amended)

Examiner: R. Landsman

AMENDMENT AND REPLY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed August 24, 2004 (Paper No. 081704) please enter the following amendments and consider the following remarks. Applicants submit concurrently herewith: (a) Fee Transmittal Sheet (in duplicate), with appropriate fee.

Amendments to the Claims begin on page 2.

Remarks begin on page 6.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims.

1-41. **(Cancelled)**

42. **(Currently Amended)** A method of treating a patient having an injury to or a disorder of an eye, said injury or disorder comprising degeneration of a photoreceptor cell, said method comprising administering to a patient a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2, which includes the eight conserved cysteines at amino acids 108, 133, 139, 142, 143, 150, 186 and 188 in an amount sufficient to proliferate photoreceptor cells.

43. **(Previously Presented)** The method of claim 42, wherein the polypeptide is attached to a water soluble polymer.

44. **(Previously Presented)** The method of claim 43, wherein the water soluble polymer is polyethylene glycol.

45. **(Canceled)**

46. **(Previously Presented)** The method of claim 42, wherein the polypeptide is administered as a sustained-release pharmaceutical composition.

47. **(Previously Presented)** The method of claim 42, wherein the polypeptide is administered as a topical pharmaceutical composition.

48. **(Previously Presented)** The method of claim 42, wherein the polypeptide is administered as an oral pharmaceutical composition.

49. **(Previously Presented)** The method of claim 42, wherein the polypeptide is administered as a parenteral pharmaceutical composition.

50. **(Previously Presented)** The method of claim 42, wherein the polypeptide is administered at a dose between about 0.005 mg/kg and about 50 mg/kg body weight.

51. **(Previously Presented)** The method of claim 50, wherein the polypeptide is administered at a dose between about 0.05 mg/kg and about 5 mg/kg body weight.
52. **(Previously Presented)** The method of claim 42, wherein the polypeptide comprises amino acids 80 to 202 of SEQ ID NO:2.
53. **(Previously Presented)** The method of claim 52, wherein the polypeptide is attached to a water soluble polymer.
54. **(Previously Presented)** The method of claim 53, wherein the water soluble polymer is polyethylene glycol.
55. **(Canceled)**
56. **(Previously Presented)** The method of claim 52, wherein the polypeptide is administered as a sustained-release pharmaceutical composition.
57. **(Previously Presented)** The method of claim 52, wherein the polypeptide is administered as a topical pharmaceutical composition.
58. **(Previously Presented)** The method of claim 52, wherein the polypeptide is administered as an oral pharmaceutical composition.
59. **(Previously Presented)** The method of claim 52, wherein the polypeptide is administered as a parenteral pharmaceutical composition.
60. **(Previously Presented)** The method of claim 52, wherein the polypeptide is administered at a dose between about 0.005 mg/kg and about 50 mg/kg body weight.

61. **(Previously Presented)** The method of claim 60, wherein the polypeptide is administered at a dose between about 0.05 mg/kg and about 5 mg/kg body weight.
62. **(Previously Presented)** The method of claim 42, wherein the polypeptide comprises amino acids 9 to 396 of SEQ ID NO:2.
63. **(Previously Presented)** The method of claim 62, wherein the polypeptide is attached to a water soluble polymer.
64. **(Previously Presented)** The method of claim 63, wherein the water soluble polymer is polyethylene glycol.
65. **(Canceled)**
66. **(Previously Presented)** The method of claim 62, wherein the polypeptide is administered as a sustained-release pharmaceutical composition.
67. **(Previously Presented)** The method of claim 62, wherein the polypeptide is administered as a topical pharmaceutical composition.
68. **(Previously Presented)** The method of claim 62, wherein the polypeptide is administered as an oral pharmaceutical composition.
69. **(Previously Presented)** The method of claim 62, wherein the polypeptide is administered as a parenteral pharmaceutical composition.
70. **(Previously Presented)** The method of claim 62, wherein the polypeptide is administered at a dose between about 0.005 mg/kg and about 50 mg/kg body weight.
71. **(Previously Presented)** The method of claim 70, wherein the polypeptide is administered at a dose between about 0.05 mg/kg and about 5 mg/kg body weight.

72. **(Canceled)**

73. **(Previously Presented)** The method of claim 42, wherein the injury or disorder is selected from the group consisting of age-related macular degeneration, diabetic retinopathy, peripheral vitreoretinopathies, photic retinopathies, surgery-induced retinopathies, viral retinopathies, ischemic retinopathies, retinal detachment and traumatic retinopathy.

74. **(Previously Presented)** The method of claim 52, wherein the injury or disorder is selected from the group consisting of age-related macular degeneration, diabetic retinopathy, peripheral vitreoretinopathies, photic retinopathies, surgery-induced retinopathies, viral retinopathies, ischemic retinopathies, retinal detachment and traumatic retinopathy.

75. **(Previously Presented)** The method of claim 62, wherein the injury or disorder is selected from the group consisting of age-related macular degeneration, diabetic retinopathy, peripheral vitreoretinopathies, photic retinopathies, surgery-induced retinopathies, viral retinopathies, ischemic retinopathies, retinal detachment and traumatic retinopathy.

76. **(Canceled)**

REMARKS

Claims 42-44, 46-54, 56-64, 66-71 and 73-75 are pending.

Rejections under 35 U.S.C. §112, first paragraph – new matter

The Examiner has rejected claims 42-44, 46-54, 56-64, 66-71 and 73-75 under 35 U.S.C. §112, first paragraph as introducing new matter by reciting amino acids 108-188 of SEQ ID NO:2. As pointed out in Applicants' previous response, amino acids 108-188 of SEQ ID NO:2 correspond to the conserved domain found within PDGF/VEGF family members that contains 8 conserved cysteines. This conserved domain is discussed throughout the application. *See*, for example, page 2, lines 7-9; page 11, lines 15-17 and 26-30; page 53, lines 9-12; and Figures 3A-3B. However, the Examiner asserts that this disclosure is insufficient because "nowhere in the specification does it refer to this exact domain" and "Residues 80-188 neither end, nor begin, with cysteines" and because "it appears that this region contains 9 cysteines." Applicants respectfully traverse.

By asserting that "nowhere in the specification does it refer to this exact domain," The Examiner appears to require that the specification specifically contain, *verbatim*, the language "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2." Applicants respectfully disagree.

It is well established that an amendment to claim need not be supported verbatim in the specification. *See, e.g., ICN Photonics, Ltd. v. Cynosure, Inc.*, 73 F3d. Appx. 425 (Fed. Cir. 2003) ("Indeed, different language that expresses the same meaning found in the originally filed specification may be sufficient."), *citing Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). The test for determining whether or not a claim limitation added by amendment introduces new matter is whether "one skilled in the art, reading the original disclosure, [would] immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). *See also, Tronzo v. Biomet, Inc.* 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("[T]he missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure.") and *Fujikawa v. Wattanasin*, 93 F.3d at 1570 ("The disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question.").

Applicants respectfully submit that the disclosure of the conserved domain found, for example, at page 2, lines 7-9; page 11, lines 15-17 and 26-30; page 53, lines 9-12; and Figures 3A-3B of the instant specification would "reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question," even though the language "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2" is not found in the specification *verbatim*. That is, the fact that the specification does not refer to the domain as "amino acids 108 to 188 of SEQ ID NO:2" does not render this claim limitation new matter.

The disclosure at page 11, lines 15-17 clearly indicates that "it is particularly important that all eight cysteines are conserved within all four members of the [PDGF/VEGF] family (see boxed areas of Figure 3)." Also at page 11, lines 26-30, the specification indicates that "active fragments are meant to include any portions of the full length amino acid sequence which have less than the full 419 amino acids of the full amino acid sequence as shown in SEQ ID NO:2, ***but still contain the eight cysteine residues shown conserved in Figure 3.***" Thus, a skilled artisan would easily recognize the importance of the conserved 8 cysteine domain. Upon comparing Figure 3 and SEQ ID NO:2, one of skill in the art could readily determine the amino acid numbering (in SEQ ID NO:2) of the eight boxed cysteine residues shown in Figure 3, i.e., the conserved cysteines correspond to amino acid residues 108, 133, 139, 142, 143, 150, 186 and 188. Thus, the conserved domain spans amino acid residues 108 to 188 of SEQ ID NO:2. Thus, one of skill in the art would clearly understand that Applicants' had possession of the subject matter in question.

Applicants are confused as to the Examiner's assertion that "[r]esidues 80-188 neither end, nor begin, with cysteines." The claims do not recite "residues 80-188." However, Applicants will respond to this rejection assuming that the Examiner meant to refer to "residues 108-188." As enumerated above, when the boxed cysteine residues of Figure 3 are matched with the corresponding residues of SEQ ID NO:2, the conserved 8 cysteines correspond to amino acid residues 108, 133, 139, 142, 143, 150, 186 and 188. Thus, contrary to the Examiner's assertion "[r]esidues 108-188" do begin and end with cysteines.

Furthermore, the fact that this region may include 9 cysteines is not relevant to the inquiry of whether or not one of skill in the art would understand that Applicants' had possession of the claimed subject matter. Figure 3 clearly indicates the 8 conserved cysteine residues. One of skill in the art would therefore understand what is meant by "the conserved 8 cysteines" even

if the domain spanning amino acid residues 108-188 of SEQ ID NO:2 contains 9 cysteines. The 9th cysteine, found at amino acid residue 114 of SEQ ID NO:2 is not boxed in Figure 3.

For the reasons provided above, Applicants respectfully submit that the claims, as previously pending did not introduce new matter. However, in the interest of advancing prosecution, Applicants have amended claim 42 to recite "a polypeptide comprising amino acids 108 to 188 of SEQ ID NO:2, which includes the eight conserved cysteines at amino acids 108, 133, 139, 142, 143, 150, 186 and 188" to further clarify the location of the conserved 8 cysteine amino acid residues. Applicants respectfully request withdrawal of this rejection.

CONCLUSION

The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application. Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Dated: Oct 12, 2004

Respectfully submitted,

By 
Melissa Jean Pytel

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